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EXAMINER

RAPILLO, KRISTINE K

ART UNIT

PAPER NUMBER

3626

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/675,128	Applicant(s) MILOSAVLJEVIC, NADA	
	Examiner KRISTINE K. RAPILLO	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3, 23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-22, 24-25, 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment submitted December 22, 2008. Claims 1, 2, 4, 6, 8, 22, 24 – 25, and 27 have been amended. Claims 3, 23, and 26 are cancelled. Claims 1 – 2, 4 – 22, 24 – 25, and 27 are presented for examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "simultaneously displaying the selected information" is vague and indefinite. It is unclear how the information is simultaneously displayed. For examination purposes, the Examiner has treated it as simultaneously displayed on a computer monitor.
4. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24 and 25 reference "the device of claim 22", however, no device is claimed is the amended version of claim 22.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 1 – 7 are rejected under 35 U.S.C. 101 as the claimed invention is directed to non-statutory subject matter. In order for a method to be considered a "process" under 35 USC § 101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). *Diamond v. Diehr*, 450 U.S. 175,

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184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).

If neither of these requirements is met by the claim, the method is not a patent eligible process under 35 USC § 101 and is non-statutory subject matter. With regard to claim 1, the method claimed by the Applicant is not tied to another statutory class as it recites the limitations "determining attributes of the patient...", "selecting a source of information....", "comparing the attributes of the patient....", "indicating...match an attribute of a patient", "recording data identifying the patient", and "simultaneously displaying the selected information....". The method claimed does not include a particular machine, nor does it transform the data identifying the patient. The method steps recited in the body of claim 1 could reasonably be interpreted to encompass a human being performing these steps. The citation "recording data" includes only a nominal recitation of an apparatus. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. Claims 2 – 7 have similar deficiencies as noted above with regard to claim 1 and therefore are rejected for substantially the same reason.

7. Claims 8 - 21 are rejected under 35 U.S.C. 101. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). For instance, the method steps recited in the body of claim X could reasonably be interpreted to encompass a human being performing these steps. Claims XXX have similar deficiencies as noted above with regard to claim 1 and therefore are rejected for substantially the same reason.

8. Claims 22 – 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For instance, claim 22 is a system claim, however there are no hardware components, as is expected with a system claim, in the limitations. Claims 23 – 27 have similar deficiencies as noted above with regard to claim 1 and therefore are rejected for substantially the same reason.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 – 2, 4 – 22, and 25 - 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, herein after Campbell (U.S. Patent Number 6,047,259) in view of Blasingame, herein after Blasingame (U.S. Pub. No. 2002/0022975).

In regard to claim 1 (Currently Amended), Campbell teaches a method for facilitating the evaluation, diagnosis and treatment of a patient suspected of having a medical disorder (column 2, lines 2 – 4), comprising: determining attributes of the patient and making a preliminary diagnosis based on the attributes that a patient has a particular medical disorder (column 7, lines 35 – 41) where Campbell discloses a rule out list and tentative diagnosis; comparing the attributes of the patient to the information about the particular medical disorder on the template (column 7, lines 42 – 47 and column 17, lines 3 – 7) where actual observations are compared to observations associated with ailment; and, simultaneously displaying on the template the information about the particular medical disorder, the matching indicia and the patient data (column 11, lines 11 – 29 and lines 46 – 49). The examiner interprets attributes to include patient information such as smoking, obesity, etc since an attribute is a quality or characteristic or ascribing to someone or something.

Blasingame teaches a method of providing a template including information about the particular medical disorder (paragraphs [0086] and [0088] where the MI system disclosed by Blasingame will ask the patient questions based on the health conditions selected by the physician) and at least one field for recording data corresponding to the attributes of the patient (Figures 7A-C, 8A-E, and 9A-C) where check boxes and data fields are presented in the template; marking the template to indicate information about

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the particular medical disorder that matches an attribute of the patient (paragraph [0127]) where a user can check the appropriate box, or annotate in an editable box, on the template, thus marking the template; recording data identifying the patient (paragraphs ([0077] and [0099 through 0104]), and wherein the step of determining is performed before the steps of providing, comparing, marking, and displaying (paragraph [0086]) where potential conditions can be determined based on a patient's health complaints prior to an office visit, thus the determining step is performed prior to the steps of providing, comparing, marking, and displaying.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a method of providing a template including information about the particular medical disorder and at least one field for recording data corresponding to the attributes of the patient; marking the template to indicate information about the particular medical disorder that matches an attribute of the patient; recording data identifying the patient; and wherein the step of determining is performed before the steps of providing, comparing, marking, and displaying as taught by Blasingame, within the method of Campbell, with the motivation of improving doctor-patient communication by offering condition-specific information – i.e. information specific to a particular medical disorder (paragraph [0008]) in Blasingame. Both doctors and patients supply the information via a medical information system, which is accessible via a computer system.

In regard to claim 2 (Currently Amended), Campbell and Blasingame teach a method to evaluate, diagnose and treat a patient suspected of having a medical disorder as per claim 1.

Blasingame teaches a method wherein the information about the medical disorder comprises at least one sign or symptom of the medical disorder (paragraphs [0221] through [0275] with accompanying Figures 17C and D), at least one test used to confirm or evaluate the medical disorder (paragraphs [0221] through [0275] with accompanying Figures 17C and D), and at least one treatment for the medical disorder (paragraphs [0221] through [0275] with accompanying Figures 17C and D).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a method in which the information in the source about a medical disorder comprises at

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least one sign or symptom of the medical disorder, at least one test used to confirm or evaluate the medical disorder, and at least one treatment for the medical disorder as taught by Blasingame with the motivation of providing a focused office visit with a physician or health care provider by enabling the physician to utilize the most recent medical advances (i.e. tests, treatments) documented in the information source (paragraph [0011]), as suggested by Blasingame.

In regard to claim 4 (Currently Amended), Campbell and Blasingame teach a method where an information source consists of a template with information on one or more medical disorders as per claim 1.

Blasingame teaches wherein the template is a printed sheet (paragraph [0124]).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a method where the template is a printed sheet as taught by Blasingame with the motivation of retaining the sheet for a patients medical record, stored in the physicians office file (paragraph [1033]) as suggested by Blasingame.

In regard to claim 5 (Original), Campbell and Blasingame teach the method of claim 4. Campbell and Blasingame do not expressly show wherein the sheet is erasable and reusable.

However, these differences are only found in the nonfunctional descriptive material and do not alter how the template functions (i.e. the descriptive material does not reconfigure the display). Thus, the descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to erase and reuse the sheet because such data does not alter how the template functions and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

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In regard to claim 6 (Currently Amended), Campbell and Blasingame teach a method where the template is a printed sheet, as per claim 1.

Blasingame teaches wherein the source is a computerized database and the template is a computer-generated visual display (paragraphs [0125] through [0130]).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a method where the source is a computerized database and the template is a computer-generated visual display as taught by Blasingame with the motivation of allowing both physicians and patients the ability to receive and display medical information at their convenience (paragraph [0077]) as suggested by Blasingame.

In regard to claim 7 (Original), Campbell and Blasingame teach a method as per claim 1. Campbell teaches a method of transmitting matching indicia and patient data from a health care practitioner making the selection including matching indicia and patient data from a health care practitioner making the selection (column 17, lines 3 – 7).

Blasingame teaches transmitting selected information comprising: Indication or recordation to another health care practitioner (paragraph [0106]) where the information available is provided only if the patient authorizes the transfer (the information is transferred following the same process as taught by Campbell above) and the patient's medical record (paragraph [0012]).

The motivation for combining the teachings of Campbell and Blasingame is discussed in the rejection of claim 6.

In regard to claim 8 (Currently Amended), Campbell teaches a method for managing patient medical information using a computer system having data storage means and a display (column 3, lines 43 – 46), the method comprising:

- Retaining in the storage means a database of information related to medical conditions (column 4, lines 43 – 52);

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- Making a preliminary diagnosis that a patient is afflicted with a particular one of said medical conditions (Figure 9: column 3, lines 1 – 4; column 2, lines 22 – 31; and column 7, lines 42 – 56);
- Retrieving from the database information relating to said particular one of said medical condition (Figures 4 and 9; column 4, lines 43 – 52; and, column 17, lines 3 - 7) where observations associated with an ailment are compared with observations from an actual exam;
- Entering patient data into the storage means (column 4, lines 56 – 60); and
- Simultaneously displaying the retrieved information and the patient data on the display (column 11, lines 11 –29 and lines 46 – 49)

Blasingame teaches a method wherein the step of making a preliminary diagnosis is performed before the steps of retrieving and entering (paragraph [0086]).

The motivation to combine the teachings of Campbell and Blasingame is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 9 (Original), Campbell and Blasingame teach a method, as per claim 8. Campbell teaches a method further comprising displaying additional reference information not limited to the medical condition or patient data (column 18, lines 1 – 6).

In regard to claim 10 (Original), Campbell and Blasingame teach a method, as per claim 8, for managing patient medical information using a computer system.

Blasingame teaches a method wherein the database comprises information on the etiologies of said medical conditions (paragraphs [0063] and [0064]; figures 17A and 17B). Figures 17A and 17B illustrate condition specific physician reports which detail the possible causes or origins of a medical condition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the database comprises information on the etiologies of said medical conditions as taught by Blasingame in view of the teachings of Campbell with the motivation of providing the physicians with additional tools to perform a diagnosis on a patient, including differential diagnosis

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and work-up algorithms via the use of the medical information database(paragraph [0166]) as suggested by Blasingame.

In regard to claim 11 (Original), Campbell and Blasingame teach a method, as per claim 8. Campbell further teaches a method wherein the database comprises information on the signs or symptoms of the medical conditions (column 7, lines 42 – 46).

In regard to claim 12 (Original), Campbell and Blasingame teach the method of claim 11. Campbell teaches a method wherein the displayed patient data and the retrieved medical condition information associates one of said signs or symptoms with the patient (column 17, lines 3 – 7).

In regard to claim 13 (Original), Campbell and Blasingame teach a method as per claim 8, for managing patient medical information using a computer system.

Blasingame teaches a method wherein the database comprises information on differential diagnoses of the medical conditions (paragraphs [0089] and [0166]).

The motivation for combining the teachings of Campbell and Blasingame is discussed in the rejection of claim 10.

In regard to claim 14 (Original), Campbell and Blasingame teach the method of claim 8. Campbell teaches a method wherein the database comprises information on diagnostic tests or work-up procedures used to confirm or evaluate the medical conditions (Figure 10 and column 17, lines 45 –52). Figure 10 illustrates a diagnostic protocol in which a diagnosis is selected with database generated treatment options, including diagnostic test/work-up procedures. A work-up procedure includes any type of test performed on a patient, including fluids, tissues, secretions, and excretions. The examiner interprets diagnostic test and work-up procedure to be equivalent as both are laboratory tests used to confirm or rule out a medical disorder.

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In regard to claim 15 (Original), Campbell and Blasingame teach the method of claim 14. Campbell teaches a method wherein the displayed patient data and the retrieved medical condition information associates one of said tests or a portion of said work-up with the patient (Figures 9 and 10, where Figure 9 illustrates patient data and Figure 10 illustrates recommended diagnostic tests/work-up procedures).

In regard to claim 16 (Original), Campbell and Blasingame teach a method, as per claim 8. Campbell teaches a method wherein the database comprises information on the treatment or management of patients with the medical conditions (column 17, lines 46 – 52; Figure 10 in Campbell teaches computer screen shots which illustrate a diagnostic protocol which is defined in the reference as a tool to manage a treatment protocol).

In regard to claim 17 (Original), Campbell and Blasingame teach a method as per claim 16. Campbell teaches a method wherein the displayed patient data and the retrieved medical condition information associates one of said treatments or management procedures with the patient (column 16, lines 66 – 67 through column 17, lines 1 – 7 and Figure 9).

In regard to claim 18 (Original), Campbell and Blasingame teach a method as per claim 8 for managing patient medical information using a computer system.

Blasingame teaches a method wherein said patient data identifies the said patient (paragraphs [0099] through [0103]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein patient data identifies the said patient as taught by Blasingame in view of the teachings of Campbell with the motivation of allowing the patient to manage personal information by inputting any editorial requirements, storage, and display of data (paragraphs [0096] and [0097]) of a medical chart as suggested by Blasingame. This allows the physician to have available any condition-specific information prior to a diagnosis/examination.

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In regard to claim 19 (Original), Campbell and Blasingame teach a method, as per claim 8. Campbell further teaches a computer-readable medium having computer-executable instructions for facilitating the performance of the method (column 4, lines 43 – 47).

In regard to claim 20 (Original), Campbell and Blasingame teach the method of claim 8. Campbell teaches a method wherein the medical information includes at least one type of information selected from each of the following four groups: (b) Sign, symptom, or abnormality (Figure 9 and column 16, lines 33 - 42) and (d) Treatment, management, follow-up, prognosis, staging criteria, or surgical indication (figures 9 and 10 and column 16, lines 45 – 54). The invention of Campbell was specifically adapted for a veterinary practice, however it is obvious that the same invention can be used for human medical use (column 1, lines 59 – 60) for the advantage of electronically diagnosis of a medical disorder.

Blasingame teaches a method wherein the medical information includes at least one type of information selected from each of the following: (a) Definition, epidemiology, etiology, background, or description (paragraphs [0063] and [0064], Figures 17A and B) and (c) Differential diagnosis, diagnostic work-up, laboratory test or data. (paragraphs [0066], [0067], [0087], [0221] through [0275], and Figures 17C and D). The examiner interprets diagnostic work-up and laboratory test to be equivalent as a diagnostic work-up is defined as any type of test performed on a patient.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a method wherein the medical information includes at least one type of information selected from each of the following: (a) definition, epidemiology, etiology, background, or description and (c) differential diagnosis, diagnostic work-up, laboratory test or data as taught by Blasingame in view of the teachings of Campbell with the motivation of providing medical information over a computer network to enhance communications between physicians and patients (paragraph [0008]) as suggested by Blasingame.

In regard to claim 21 (Original), Campbell and Blasingame teach a method as per claim 20. Campbell further teaches a method wherein said displayed medical information and patient data associates one of

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said signs or symptoms with the patient (column 16, lines 66 – 67 through column 17, lines 1 – 7 and Figure 9).

In regard to claim 22 (Currently Amended), Campbell teaches a system for use in connection with providing health care to a patient, comprising: A template populated with information on treatments that could be administered to treat the medical disorder (column 17, lines 46 – 55) where Campbell discloses a tentative diagnosis as well as recommended treatments; and at least one field for entry of patient data (Figure 4; column 12, lines 13 – 18); which is adapted to indicate the user's observation that the patient exhibits one or more of the signs and/or symptoms associated with the corresponding medical disorder (column 2, lines 4 – 31) where a user makes observations based on the examination and compares to predetermined observations; and the user's opinion that one or more of the treatments should be administered to treat the patient (column 18, line 61 through column 19, line 7) where a user can select a particular therapy to treat a patient. Campbell fails to explicitly teach a plurality of templates, however, this deficiency is cured by Blasingame.

Blasingame teaches a system comprising a plurality of printed templates (paragraph [0084]), each of the templates populated with: information on signs and/or symptoms associated with a corresponding medical disorder (paragraphs [0080] and [0083]); information on tests that could be used to determine the presence or severity of the medical disorder (paragraphs [0090], [0189], and [0211]); wherein each of said templates is adapted for annotation by a user (paragraph [0127]) to indicate: the user's opinion that one or more of the tests should be conducted to confirm that the patient is afflicted by the corresponding medical disorder (paragraph [0092], [0189], and [0204]) where tests may be needed to confirm the patient's condition; and wherein at least one of the templates is directed to a medical disorder other than the medical disorder the patient is suspected of having (Figure 10A) where Blasingame discloses a condition specific template (Asthma).

The motivation to combine the teachings of Campbell and Blasingame is discussed in the rejection of claim 1, and incorporated herein.

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In regard to claim 25 (Currently Amended), Campbell and Blasingame teach the device of claim 22. Campbell and Blasingame do not expressly show wherein each of the templates is adapted to be marked by a user such that the marks can be later removed and the template returned to its original condition and marked again.

However, these differences are only found in the nonfunctional descriptive material and do not alter how the template functions (i.e. the descriptive material does not reconfigure the display). Thus, the descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made wherein the template is adapted to be marked by a user and the marks can be later removed and the template returned to its original condition and marked again because such data does not alter how the template functions and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

In regard to claim 27 (Currently Amended), Campbell and Blasingame teach a device as per claim 22.

Blasingame teaches a device wherein the device is portable (paragraph [0080]).

The motivation for combining the teachings of Campbell and Blasingame is discussed in the rejection of claim 22.

11. Claim 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell and Blasingame as applied to claim 22 above, and further in view of Sonsteby (U.S. Patent Number 5,636,873).

In regard to claim 24 (Currently Amended), Campbell and Blasingame teach the device of claim 22.

Sonsteby teaches a device wherein one of the templates can be removed from the set of templates without damaging the remaining templates (column 1, line 66 through column 2, line 19) where Sonsteby

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discloses identical adhesive backed labels with predetermined assessment information, thus, when a label (i.e. template) is removed the remaining labels (i.e. templates) are not damaged.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method further comprising multiple copies of the templates assembled together such that one copy at a time can be removed by a user without damaging the remaining copies as taught by Sonstebly in view of Campbell and Blasingame with the motivation of educating the patient in regards to his or her medical disorder (column 4, lines 50 – 54) as suggested by Sonstebly.

Response to Arguments

12. Applicant's arguments filed December 22, 2008 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed December 22, 2008.

13. In response to the claim1, the Applicant argues that the template is an apparatus and thus ties the claims to an apparatus thereby overcoming the 35 U.S.C. 101 rejections of claims 1 – 7. The Examiner respectfully disagrees. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). For instance, the method steps recited in the body of claim 1 could reasonably be interpreted to encompass a human being performing these steps. Claims 2 - 7 have similar deficiencies as noted above with regard to claim 1 and therefore are rejected for substantially the same reason. Therefore, the 35 U.S.C. 101 rejections of claims 1 – 7 is maintained.

Claims 8 – 21 have also been rejected under 35 U.S.C. 101, as the Applicant amended the claims by removing the term “device” thereby removing the tie to a machine of the method claims (*In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008)).

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In addition, claims 22 – 27 have been rejected under 35 U.S.C. 101, as the Applicant removed the term “device” thereby eliminating any association of actual hardware (i.e. server, processor) with the system in the body of the claims.

14. In response to the Applicant’s argument, it is respectfully submitted that the Examiner has applied new passages and new citations to the amended claims. The Examiner notes that the amended limitations were not in the previously pending claims; as such, Applicant’s remarks with the regard to the application of Campbell and Blasingame are addressed in the above Office Action.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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KKR

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